DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0302]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certain Biologics Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Certain Biologics Labeling

Under the authority of section 351 of the Public Health Services Act (42 U.S.C. 262), the biologics regulations in part 601 (21 CFR part 601) require a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce (§ 601.2). In addition, § 601.12 requires that any changes to labeling be submitted to FDA for review and approval. For biological products, excluding blood and blood components for transfusion, the container and package labeling requirements subject to the PRA are provided in §§ 610.60 through 610.62 (21 CFR 610.60 through 610.62). The collections of information under §§ 601.2, 601.12, and 610.60 through 610.62 are approved under OMB control number 0910–0338 (expires August 31, 2005). In addition to the labeling requirements prescribed in §§ 610.60 through 610.62 or other labeling regulations (e.g., 21 CFR 809.10), there are additional container and/or package labeling requirements for certain licensed biological products subject to the PRA:

- Sections 640.70 and 640.74 (21 CFR 640.70 and 640.74) (source plasma),
- Section 640.84 (albumin),
- Section 640.94 (plasma protein fraction),
- Section 660.2 (21 CFR 660.2) (antibody to Hepatitis B surface antigen),
- Section 660.28 (blood grouping reagent),
- Section 660.35 (reagent red blood cells),
- Section 660.45 (Hepatitis B surface antigen), and

• Section 660.55 (anti-human globulin).

An example of an additional labeling requirement for each of the specific regulations follows:

• Section 640.70(a), the total volume or weight of plasma;

• Section 640.74(b)(3) and (b)(4), the name of the manufacturer of the final blood derivative product for whom it was prepared;

• Sections 640.84(a) and (c), and 640.94(a), the osmotic equivalent;

• Section 660.2(c), name of the recommended test method(s);

• Section 660.28(a) and (b), the name of the antibody or antibodies present;

• Section 660.35(a), (c) through (g), and (i) through (m), information regarding washing of cells, percentage of red blood cells in suspension;

• Section 660.45, name of the recommended test method(s); and

• Section 660.55(a) and (b), the name of the antibody or antibodies present.

Form FDA 2567 ''Transmittal of Labels and Circulars'' is used by manufacturers of licensed biological products to submit with labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. Labeling information is submitted to FDA for review in an application, supplement, or, when appropriate, an annual report. Form FDA 2567 is approved under OMB control number 0910–0338.

Based on information obtained from the Center for Biologics Evaluation and Research's database system, there are an estimated 350 manufacturers of licensed biological products. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions for a particular product (e.g., license applications and labeling supplements) received annually by FDA. No applications have been received for most of the listed products in the last couple of years, but FDA is using the estimate of

one application in the event that one is submitted in the future. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years.

The hours per response are based on FDA's past experience with the various submissions to FDA and includes the time estimated to prepare the various submissions for FDA review and collate the documentation. The burden associated with the additional labeling requirements for submission in a license application is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.62 or other labeling requirements. FDA estimates that it takes between 10 and 40 hours (average 25 hours) to complete a labeling supplement or annual report for submission to FDA.

In the **Federal Register** of July 22, 2003 (68 FR 43359), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
640.70(a), and 640.74(b)(3) and (b)(4)	application	5	1	5	2	10
	supplement	20	1.5	30	25	750
640.84(a) and (c)	application	1	1	1	1	1
	supplement	3	1.25	4	25	100
640.94(a)	application	1	1	1	1	1
	supplement	1	1	1	25	25
660.2(c)	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.28(a) and (b)	application	1	1	1	6	6
	supplement	1	2	2	25	50
660.35(a), (c) through (g), and (i) through (m)	application	1	1	1	6	6
	supplement	1	1	1	25	25
660.45	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.55(a) and (b)	application	1	1	1	6	6
	supplement	1	1	1	25	25

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Part	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total						1,061

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S